

Department for Environment, Food and Rural Affairs

Guidance for Metered Dose Inhaler Producers

Guidance: F Gas and Ozone Regulations

Information Sheet MDI 1: Overview

April 2012

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For current guidance search GOV.UK for "F Gas"

This Information Sheet relates to the production of Metered Dose Inhalers (MDIs) containing F gases. Certain obligations apply to the production and supply of products containing F gases and these obligations vary depending on the nature of the use of the product.

Please note, this Information Sheet only refers to production of MDIs. If you have any refrigeration, air-conditioning, fire fighting equipment or high voltage switchgear on your sites which contain F gases you will also have further obligations for this equipment. Refer to Information Sheet GEN 3 to check whether you have any other uses of F gases.

Summary of Key Obligations under the EU F Gas Regulation

The supply of MDIs is only lightly affected by the requirements of EU Regulation 842/2006 and the GB Fluorinated Greenhouse Gases Regulations 2009 (Statutory Instrument No 261¹). However it is important that MDI producers take a lead in acting responsibly, both in fulfilling their own obligations and in communicating the impacts of F gases contained within MDIs to their customer base. The obligations for MDI producers are as follows:

Reporting	Producers must report to the Commission and the Member State if they are directly importing more than 1 tonne of F gas from outside the EU.
Recovery	Fluid recovery must take place at end of life of containers used for supply of F gases ² .
Training	Where any recovery activities are performed, personnel must be appropriately qualified or alternatively a suitably qualified sub-contractor should be used.
Taking delivery	Companies taking delivery of containers of F gas need to employ personnel with appropriate qualifications if undertaking F gas recovery.

Who is responsible for meeting these obligations?

The obligations listed above are the responsibility of the MDI producers. Importers and distributors of MDIs have no obligations under the EU F gas Regulation. However they do have a duty of care to ensure that their products are used responsibly and efforts are made to recover old MDIs for destruction where practicable.

¹ See Information Sheet GEN 4 for a list of relevant regulations and links to download the full text.

² Note this refers to transport containers not actual MDIs

Some Critical Dates

4 th July 2007	Refrigerant recovery from end of life containers. Recovery should be undertaken by personnel with appropriate qualifications .
1 st April 2008	Reporting of F gas import/export activity.

Further Action

A working group involving producers and importers of MDIs has been formed to look at future activities to further minimise potential emissions from this sector. This group has recently reported; a summary of feedback is given:

- That it is a good practice to ensure that F gases contained in “reject” MDIs created during the manufacturing process are handled in an environmentally responsible manner.
- Setting up additional recycling programs solely to get patients to return unused MDIs for appropriate disposal would not be constructive or cost-effective.
- A working group on Novel Medical Propellants has been established to evaluate the safety and other performance characteristics of potential future medical propellants.
- The size and design of the valve of an MDI impacts the amount of propellant required. Typically, a smaller valve size means a reduced emission per dose. R&D on new devices will look at using the smallest valve possible consistent with safety and other technical performance characteristics.

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Other Relevant Information for MDI Producers

Defra has a series of Information Sheets that are intended to help producers understand their obligations under the EU F gas and Ozone Regulations.

The following information sheets may be of relevance:

Number	Content of Information Sheet
<i>Information Sheets on MDI Issues</i>	
MDI 1	Short overview of obligations on MDI producers.
<i>Information Sheets on Refrigeration and Air-conditioning Issues</i>	
RAC 1	Short overview of issues for users of RAC Systems.
RAC 2	Background to F gas and ODS use in RAC Systems. Sources of emissions. Emission reduction opportunities. Alternative refrigerants.
RAC 3	Detailed description of key obligations for companies.
RAC 4	Getting started – advice on the steps to take to achieve compliance.
RAC 5	Qualifications & certification – details about the training and certification requirements for RAC personnel and contracting companies.
RAC 6	Practical Guidance – dealing with numerous detailed RAC topics including: leak testing, refrigerant recovery, record keeping and labelling of equipment.
RAC 7	Alternative Refrigerants – minimising emissions and options for refrigerant selection
RAC 8	HCFE Phase-out
<i>General F Gas and ODS Information Sheets</i>	
GEN 1	Glossary of terms related to F gas and ODS Regulations
GEN 2	Background to F gas and ODS fluids
GEN 3	Overview of markets and equipment affected by the F gas and ODS Regulations
GEN 4	Links to full copies of all relevant Regulations and legislation
GEN 5	Guidance on estimating refrigerant charge.

The information in this document is intended as guidance and must not be taken as formal legal advice or as a definitive statement of the law. Ultimately only the courts can decide on legal questions and matters of legal interpretation. If you have continuing concerns you should seek legal advice from your own lawyers.

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